

Agenda
CVM Listening Session
August 1, 2011, 8 am – 4 pm MST
USFWS Bozeman Fish Technology Center

The purpose of the CVM Listening Session (LS) is to discuss ways to improve the efficiency of making safe and effective aquaculture drugs available. By calling this a listening session, we intend for each party (data generators, sponsors, end users, and CVM) to listen to each other, understand each other's interests better, and generate viable ideas to make the approval process better. Although parties may feel that they represent competing commitments, we share a goal, namely getting aquaculture drugs that work and are safe to market.

Below is the agenda for the first of what we hope will be several LS, and can see that it is an ambitious agenda. Because the processes and issues we hope to address are complex, we expect success will take many different forms. In some cases, we may be able to resolve the questions during this session. In other cases, we will need to come up with action items, working groups, and timelines. These action items will be taken up and acted upon prior to the next summit of stakeholders. In any case, our job is to hear each other's concerns, address those concerns, and create a path to resolve our differences in pursuit of our goal: working together to serve the aquaculture community.

8:00 – 8:10 am – Welcome, introduction, and goal of the Listening Session – Jim Bowker

8:10 – 8:30 am – Meeting format and role of facilitator – Eric Dubbin

8:20 – 11:00 am - Data requirements for efficacy and target animal safety (TAS)

1. Data requirements using traditional studies
 - a. CVM's current thinking on data requirements
 - b. Data requirements for drugs with different modes of action
 - c. Data requirements for marine finfish
 - d. Conducting studies at one site to complete an effectiveness technical section - can it be done and are there criteria to minimize location bias?
2. Effective use of pharmacokinetic and MIC data to support effectiveness, TAS, and residue depletion studies
3. Pathogen grouping
 - a. Input from fish health experts
 - b. Expanding approval from single pathogen species to other species or genera
4. Strategies to reduce the number of TAS studies and associated data collection to complete technical section
 - a. Acute (mortality only) vs. chronic (pathologies)
 - i. Margins of safety initially established by mortality have not been revised following histological examination.
 - b. Conduct multiple acute safety studies, conduct few chronic target animal safety studies
 - c. Effective utilization of preliminary study data to determine which tissues will be affected by overdosing/overexposing

5. Acceptance of safety data from studies that were not conducted in compliance with Good Laboratory Practices
 - a. Expand the number of facilities capable of conducting TAS studies
 - b. List of critical elements that must be in compliance
6. Use of publicly available literature and INAD data
 - a. More effective use of publicly available literature – can it be used to replace/substitute traditional studies
 - i. Likelihood of obtaining raw data from published studies
 - b. Criteria for use of information in journal articles to reduce the number of required pivotal efficacy trials
 - c. Criteria for use of INAD data to reduce the number of required pivotal efficacy trials

11:00 – 11:30 pm - Labeling

1. New claims for approved drugs
2. Review of revised label submissions beyond the portion affected by new claims
3. Indexed drugs
 - a. Change “Not approved by FDA” to “Drugs must be approved, conditionally approved, or Indexed by FDA; this drug is Indexed”

11:30 am – 1 pm LUNCH

1:00 – 2:15 pm – Human Food Safety Team

1. Use of publicly available literature
2. Use of risk-based approach
3. Consideration of both “positive” and “negative” human food safety outcomes
4. Use of non-GLP studies
5. Residue depletion studies
 - a. Multiple species
 - b. Withdrawal period
 - c. Using PK data to identify a single fish species to test in the marker residue depletion study
6. Addressing GFI 152
7. Addressing toxicology requirements
 - a. Use of GRAS decisions
 - b. Use of “extensive” historical or current use
8. Food Use Authorization

2:15 – 3:15 pm – Environmental

1. Discuss strategies by which the need for EAs or revised/updated EAs for aquaculture drugs can be reduced, including categorical exclusions or abbreviated EAs for 1) prospective drugs for which no discharge will be permitted, and 2) drugs that are currently approved (for major or minor species use) and for which label expansion will minimally increase the volume of usage (e.g., $\leq 1\%$).
2. Discuss strategies by which publicly available data and published literature may be used in partial or complete fulfillment of the Environmental Technical Section.

3:15 -4:00 pm – Wrap-up

1. Summary and General Comments
2. Action items
3. Next Listening Session

FINAL - 21 July 2011